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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-1818]

Steris Laboratories, Inc.; Withdrawal of Approval of 55 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 55 abbreviated new drug applications (ANDA's). Steris Laboratories, Inc., notified the agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

EFFECTIVE DATE: (Insert date 30 days after date of publication in the FEDERAL REGISTER.)

FOR FURTHER INFORMATION CONTACT: Olivia A. Pritzlaff, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION: Steris Laboratories, Inc., 620 North 51st Ave., Phoenix, AZ 85043-4705, has informed FDA that the drug products listed in the following table are no longer marketed and has requested that FDA withdraw approval of the applications. Steris Laboratories, Inc., has also, by its request, waived its opportunity for a hearing.

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NWL 1

ANDA No.	Drug
40-043	Edrophonium Chloride Injection USP, 10 milligrams (mg)/milliliter (mL)
40-044	Edrophonium Chloride Injection USP, 10 mg/mL
62-788	Neomycin and Polymyxin B Sulfate and Gramicidin Ophthalmic Solution
62-900	Clindamycin Phosphate Injection USP, 150 mg/mL
63-079	Clindamycin Phosphate Injection USP, 150 mg/mL
70-019	Furosemide Injection USP, 10 mg/mL
70-170	Metronidazole Injection, 500 mg
70-604	Furosemide Injection USP, 10 mg/mL
70-713	Haloperidol Injection USP, 5 mg/mL
70-744	Haloperidol Injection USP, 5 mg/mL
70-911	Diazepam Injection, 5 mg/mL (ampule)
70-930	Diazepam Injection USP, 5 mg/mL (syringe)
71-556	Sulfamethoxazole and Trimethoprim for Injection Concentrate USP, 80 mg/mL and 15 mg/mL
71-339	Naloxone Hydrochloride Injection USP, 0.4 mg/mL
73-488	Fentanyl Citrate Injection USP, 50 micrograms (mcg)/mL
73-520	Droperidol Injection USP, 2.5 mg/mL
73-521	Droperidol Injection USP, 2.5 mg/mL
73-523	Droperidol Injection USP, 2.5 mg/mL
74-228	Etoposide Injection, 20 mg/mL
83-362	Prednisolone Tebutate Suspension, 20 mg/mL
83-702	Dexamethasone Sodium Phosphate Injection USP, 4 mg/mL
83-767	Prednisolone Acetate Suspension, 40 mg/mL
83-820	Brompheniramine Maleate Injection, 100 mg/mL
84-510	Promazine Hydrochloride Injection USP, 25 mg/mL

84-517	Promazine Hydrochloride Injection USP, 50 mg/mL
84-737	Hydrocortisone Sodium Succinate for Injection USP, 250 mg
84-738	Hydrocortisone Sodium Succinate for Injection USP, 100 mg
84-747	Hydrocortisone Sodium Succinate for Injection USP, 500 mg
84-748	Hydrocortisone Sodium Succinate for Injection USP, 1000 mg
84-875	Mersalyl-Theophylline Injection
85-237	Sterile Estrone Suspension USP, 2 mg/mL
85-434	Phenytoin Sodium Injection USP, 50 mg/mL
85-490	Testosterone Propionate Injection, 25 mg/mL and 50 mg/mL
85-594	Amitriptyline Hydrochloride Injection USP, 10 mg/mL
85-599	Testosterone Enanthate Injection USP, 100 mg/mL
85-606	Dexamethasone Sodium Phosphate Injection USP, 24 mg/mL
86-208	Potassium Chloride Injection
86-210	Potassium Chloride Injection
86-386	Nandrolone Phenpropionate Injection USP, 25 mg/mL
86-947	Glycopyrrolate Injection USP, 0.2 mg/mL
86-953	Methylprednisolone Sodium Succinate for Injection, 40 mg
87-030	Methylprednisolone Sodium Succinate for Injection, 125 mg
87-079	Procainamide Hydrochloride Injection USP, 100 mg/mL
87-080	Procainamide Hydrochloride Injection USP, 500 mg/mL
87-460	Mannitol Injection USP, 250 mg/mL

87-488	Nandrolone Phenpropionate Injection USP, 50 mg/mL
88-523	Methylprednisolone Sodium Succinate for Injection, 500 mg
88-524	Methylprednisolone Sodium Succinate for Injection, 1000 mg
88-554	Nandrolone Decanoate Injection, 50 mg/mL
88-772	Corticotropin for Injection USP, 40 units (vial)
89-163	Potassium Chloride for Injection Concentrate USP, 2 milliequivalents (mEq)/mL
89-170	Dexamethasone Ophthalmic Suspension USP, 0.1%
89-171	Tropicamide Ophthalmic Solution USP, 0.5%
89-421	Potassium Chloride Injection USP, 2 mEq/mL
89-606	Prochlorperazine Edisylate Injection USP, 5 mg

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of the applications listed in the table in this

document, and all amendments and supplements thereto, is hereby withdrawn, effective (insert date 30 days after date of publication in the FEDERAL REGISTER).

Dated: 6/7/99

June 7, 1999

Janet Woodcock
Director
Center for Drug Evaluation and Research